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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/356,313	07/16/1999	BERND PESCHKE	5573.210-US	7669

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EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	8

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/356,313	Peschke
Examiner	**Art Unit**
David Lukton	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 20, 2001*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above, claim(s) *13, 14, and 16-18* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-12 and 15* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicants' election of Group 1 with traverse is acknowledged (claims 1-12, 15, drawn to compounds in which M is $-C(R^{27})=C(R^{28})-$, and c +d = 0). Also acknowledged is the elected specie (the compound of example 15, page 95). Claims 13, 14, 16-18 are withdrawn from consideration.

*

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending application Serial No. 09/337809. Although the conflicting claims are not identical, they are not patentably distinct from each other; there is overlap of the claimed genera. This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application . See 37 CFR 1.78(d)

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is asserted in the specification that the claimed compounds stimulate release of growth hormone *in vivo*. However, there is no evidence that any of the claimed compounds can stimulate release of growth hormone *in vitro* or *in vivo*. The assertion by the examiner is that "undue experimentation" would be required to determine which of the compounds will be effective to induce GH secretion, and under what conditions. As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absenceprior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims. As it happens, structure/activity relationships are "unpredictable" where GH release is concerned. Consider the following:

- Torsello, Antonio (*Endocrinology* **143** (5) 1968, 2002) discloses that truncated analogs of ghrelin fail to stimulate GH release in neonatal rats.
- Tolle, V (*Neuroendocrinology* **73** (1) 54-61, 2001) discloses that certain analogs of ghrelin fail to stimulate GH release.
- Rigamonti (*Alcohol* **20** (3) 293-304, 2000) discloses that *gamma*-hydroxybutyric acid and baclofen both fail to stimulate GH release.

- Pinilla L (*Hormone Research* **51** (5) 242-7, 1999) discloses that 8-Br-cGMP was ineffective in eliciting GH release.

- Enright (*Journal of Animal Science* **71** (9) 2395-405, 1993) discloses that thyrotropin releasing hormone was ineffective in eliciting GH release

- Robberecht (*Neuroendocrinology* **56** (4) 550-60, 1992, entitled "Angiotensin II is retained in gonadotrophs of pituitary cell aggregates cultured in serum-free medium but does not mimic the effects of exogenous angiotensins and luteinizing-hormone-releasing hormone on growth hormone release") discloses that LHRH has both inhibitory and stimulatory effects on GH release in cultured pituitary cell aggregates.

Thus, it is clear that minor changes in structure can lead to elimination of activity, and that the structural features which are necessary to achieve GH secretion are "unpredictable". In one case (Robberecht, *Neuroendocrinology,* 1992) a compound exhibited both inhibitory and stimulatory effects on GH release in cell culture. Clearly, one cannot determine activity merely be viewing a structure. The claimed compounds may be effective in stimulating GH release, and they may not. Based on the information provided thus far, this cannot be determined.

In the event that only in vitro data is provided, it is suggested that the term "pharmaceutical" be deleted from claim 15. This term implies an assertion of therapeutic efficacy, which would not be in evidence even if the compounds do turn out to promote release of growth hormone.

*

Claim 15 is rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 15 is rendered indefinite because of the recitation of the phrase "effective amount". What is the amount effective for? It is suggested that the phrase "effective amount" be deleted, or else an objective of the efficacy be recited.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600